

## **REMARKS**

### **Status of the Claims**

Claims 1-14 are pending. Claim 1 is amended. Claims 1-9 are rejected under 35 USC § 112, first paragraph. Claims 10-14 are allowed.

### **Change of Correspondence Address**

Applicants respectfully bring to the attention of the Examiner the change of correspondence address for Applicant's representative. Also, enclosed, herewith, is an application of Power of Attorney/Appointment of Attorney and Change of Correspondence address.

The Examiner is always free to contact the undersigned with respect to questions regarding this application.

### **Issues Under 35 USC § 112**

The only issue precluding allowance of claims 1-9 is the rejection under 35 USC § 112, first paragraph, in which it is alleged that the claims at issue fail to comply with the written description requirement.

This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Specifically, the rejection states that the "specification fails to describe certain biomarker reference panels and what the constituents of these panels are, and fails to show how these panels

could be used to make a differential diagnosis between malignant tumor, benign tumor or control population.”

MPEP § 2163, entitled Guidelines for the Examination of Patent Applications Under the 35 USC § 112, para. 1, “Written Description” Requirement, indicates that there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. Also see *In re Wertheim*, 191 U.S.P.Q. 90, 97 (CCPA 1976), where the court emphasized this “strong presumption.” The phrase that is objected to by the Examiner was present in the claims of the originally filed application.

Furthermore, MPEP § 2163 indicates that “the examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why persons skilled in the art would not recognize that the written description of the invention provides support for the claims.” In the present case, the Examiner has offered no such objective reasoning, supported by technical journal article or the like, as to why the claims fail to satisfy the written description requirement. Additionally, the unsupported, subjective reasoning set forth in the office action failed to overcome the strong presumption set forth by the courts and USPTO policy of the strong presumption of original claims satisfying the written description requirement.

At best, the rejected claims can be described as “broad,” but such is not the standard for compliance with the written description requirement.

However, in an effort to expedite the allowance of claims 1-9, Applicants have amended claim 1 to further describe the biomarker constituents. Clear support for this amendment can be found on page 4 of the specification.

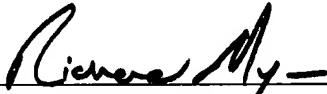
From the forgoing, further favorable reconsideration in the form of a notice of allowance of claims 1-14 is believed to be in order and such action is earnestly solicited.

Petition for an Extension of Time

Pursuant to 37 CFR § 1.136(a) applicants respectfully petition for a three-month extension of time to respond to the outstanding Office Action. Form PTO 2038 authorizing a charge of \$475.00 is attached hereto.

If the Examiner has any questions concerning this amendment, or the application in general, she is requested to contact the undersigned at the number listed below.

Respectfully submitted,

  
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